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GB 2324249 A GB 2301538 A GB 2067412 A
GB 1507309 A US 4353136 A US 4209861 A

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(54) Abstract Title

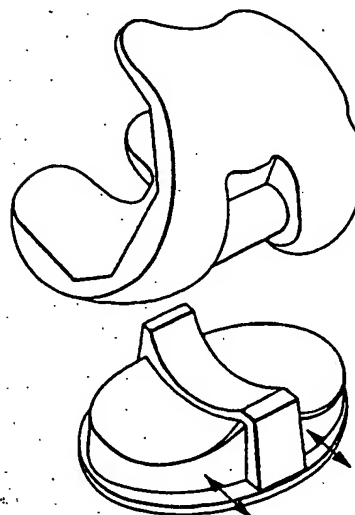
Total knee replacement capable of anterior-posterior displacement

(57) A condylar total knee replacement prosthesis is described which comprises:

(a) a femoral component having a pair of condylar surfaces;

(b) a tibial component having a tibial platform;

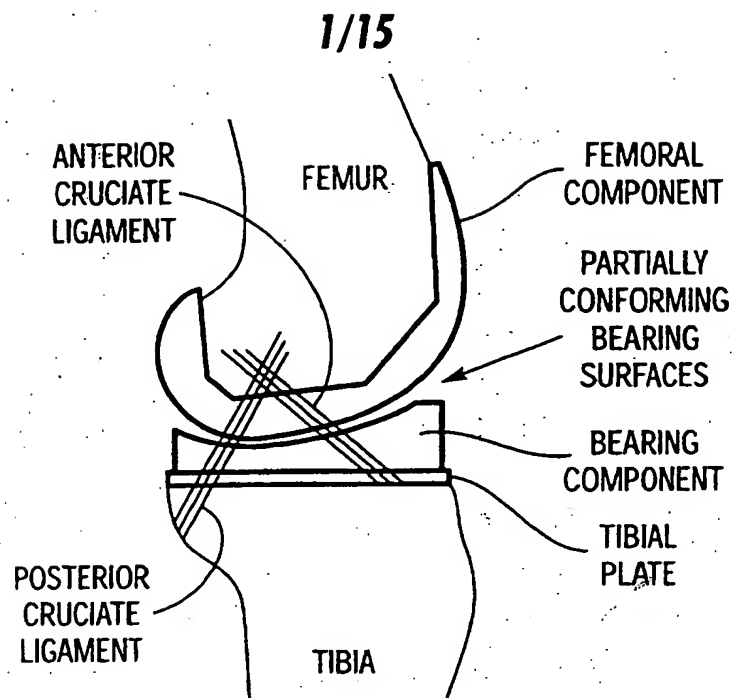
(c) bearing components interposed between the condylar surfaces and the tibial platform and having dished bearing surfaces adapted to support the femoral condylar surfaces, said femoral component having an intercondylar femoral guide surface adapted to engage the corresponding tibial guide surface, said tibial guide surface and said femoral guide surface being shaped so as to cause the femoral component to be displaced posteriorly during flexion, and displaced anteriorly during extension, and said tibial guide surface being fixed with respect to the tibial platform in an anterior-posterior (A-P) direction.



BEARING COMPONENTS SLIDE ON PLATE

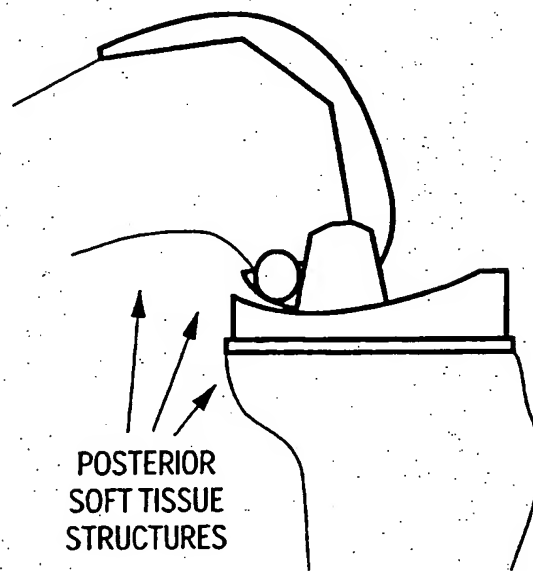
INTERCONDYLAR GUIDE SURFACES
APPLIED TO A MOBILE BEARING KNEE.
THE FEMORAL-TIBIAL BEARING SURFACES
CAN BE CLOSELY CONFORMING.

Fig.7



MECHANISMS FOR PROVIDING ANTERIOR-POSTERIOR STABILITY IN A TKR.

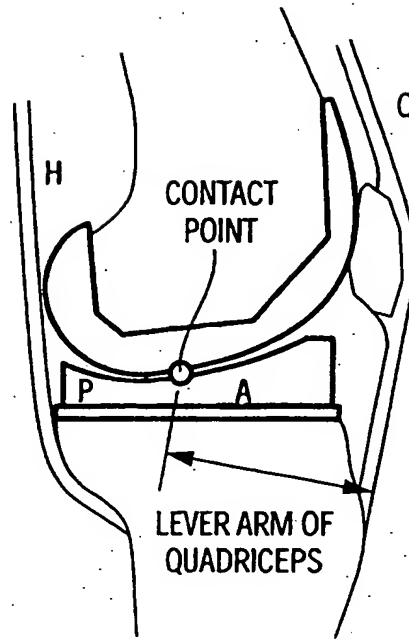
Fig. 1



THE POSTERIOR STABILISED CONCEPT WHERE A FEMORAL CAM AND TIBIAL PLASTIC POST INTERACT TO PRODUCE FEMORAL ROLL-BACK IN HIGH FLEXION.

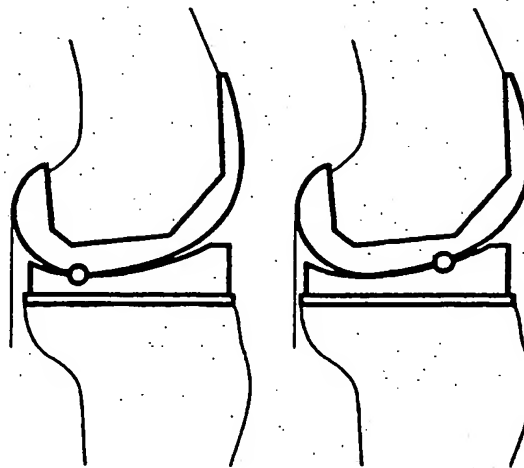
Fig. 2

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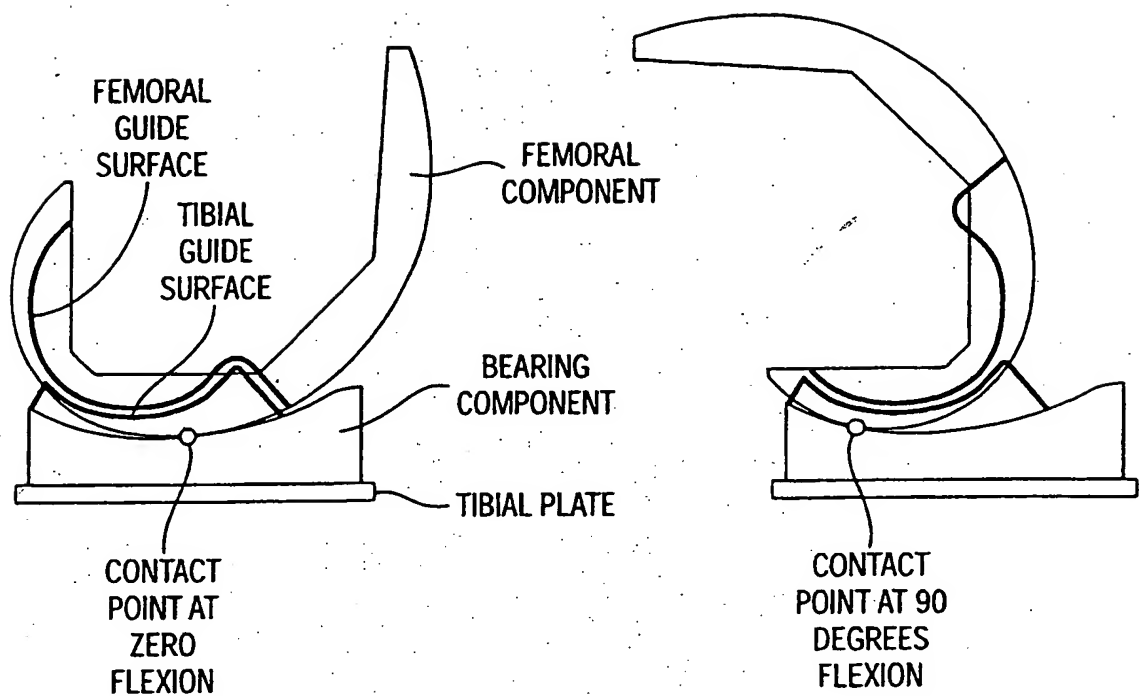
THE LEVER ARM OF A MUSCLE (QUADRICEPS Q, HAMSTRINGS H) IS DEFINED AS THE PERPENDICULAR DISTANCE BETWEEN THE MUSCLE AND THE CONTACT POINT.

Fig.3



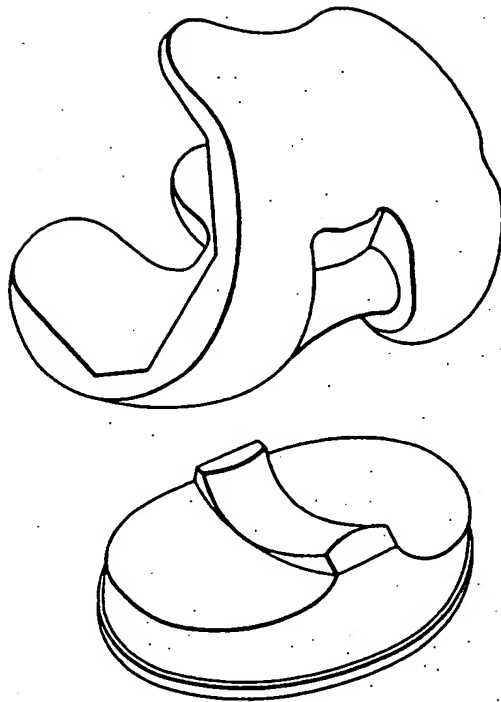
IN A TCR WITH RELATIVELY HIGH CONFORMITY BETWEEN THE BEARING SURFACES, LARGE ANTERIOR-POSTERIOR SHIFTS IN THE CONTACT POINTS CAN OCCUR FOR ONLY SMALL RIGID BODY DISPLACEMENTS.

Fig.4



TYPICAL INTERCONDYLAR GUIDE SURFACES WHICH CONTROL THE CONTACT POINTS IN THE ANTERIOR-POSTERIOR DIRECTION. THE CONTACT POINT MOVES FROM ANTERIOR TO POSTERIOR AS THE KNEE FLEXES FROM ZERO TO 90 DEGREES.

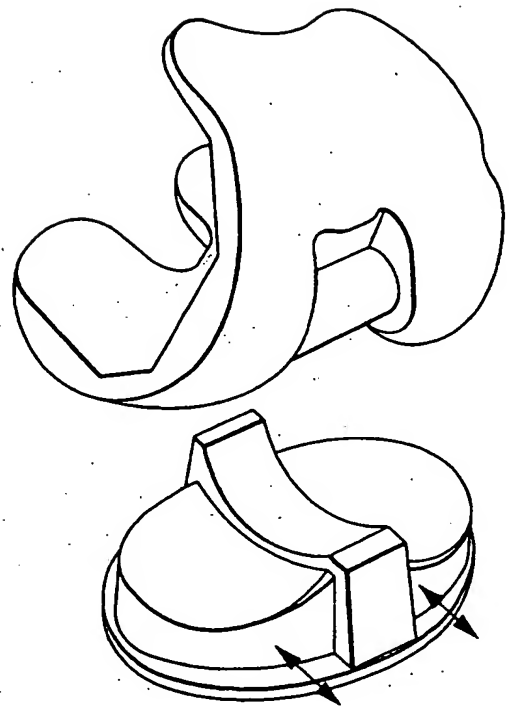
Fig.5



BEARING COMPONENT FIXED TO PLATE

INTERCONDYLAR GUIDE SURFACES APPLIED
TO A FIXED BEARING KNEE. THE TIBIAL
BEARING SURFACES NEED TO HAVE SUFFICIENT
LACK OF CONFORMITY TO ACCOMMODATE
THE ANTERIOR-POSTERIOR TRANSLATION.

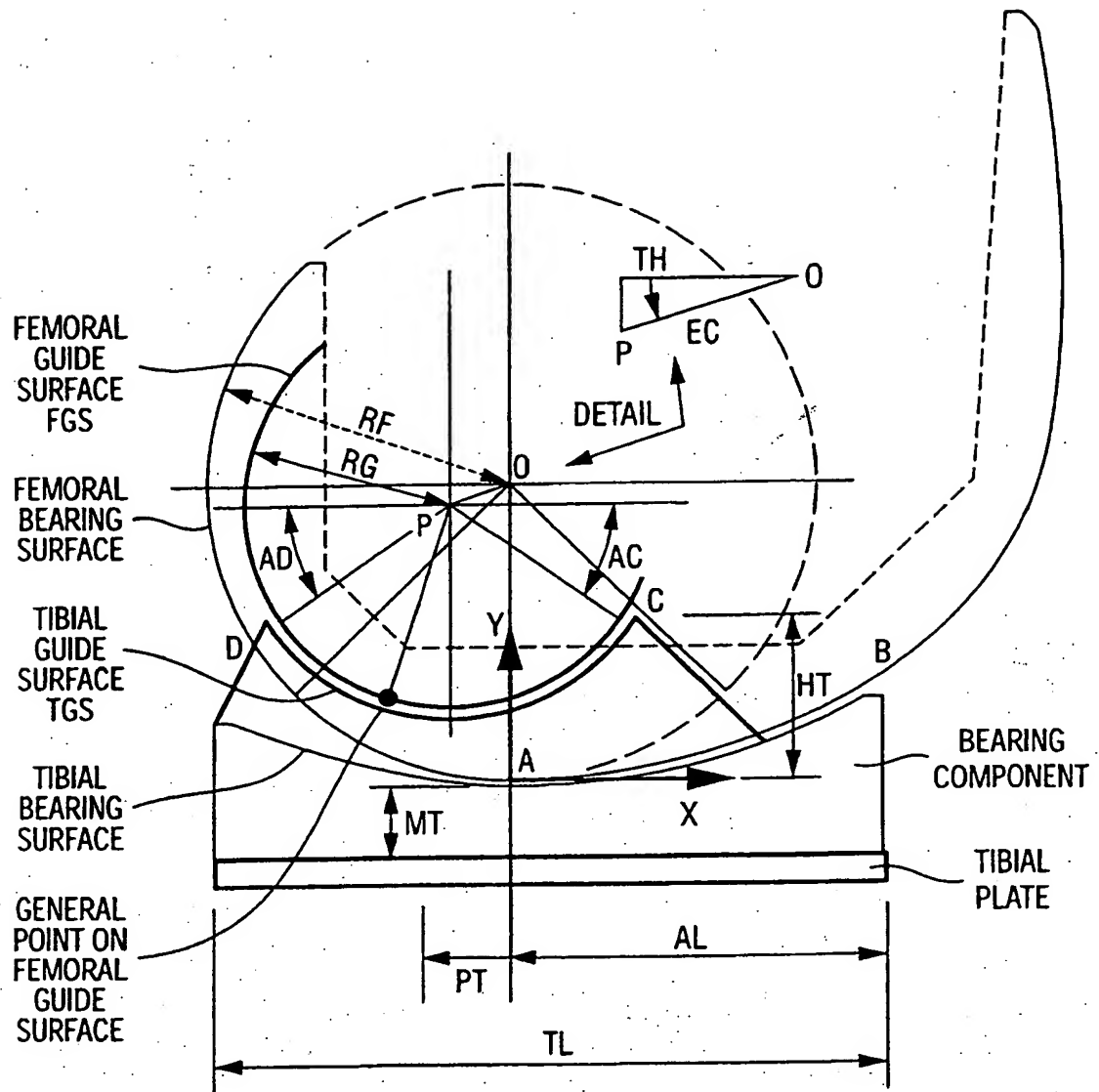
Fig.6



BEARING COMPONENTS SLIDE ON PLATE

INTERCONDYLAR GUIDE SURFACES
APPLIED TO A MOBILE BEARING KNEE.
THE FEMORAL-TIBIAL BEARING SURFACES
CAN BE CLOSELY CONFORMING.

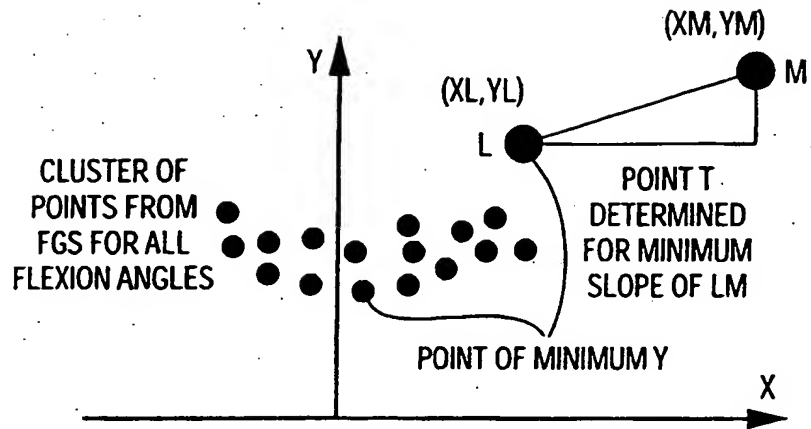
Fig.7



DEFINITION OF THE GEOMETRY OF A GENERAL FEMORAL GUIDE SURFACE. THIS GUIDE SURFACE IS USED TO GENERATE THE TIBIAL GUIDE SURFACE. THE MOST IMPORTANT DEFINITIONS ARE: O IS THE CENTER OF THE FEMORAL BEARING SURFACE, P IS THE CENTER OF THE FEMORAL GUIDE SURFACE AT ECCENTRICITY EC AND ANGLE TH FROM THE HORIZONTAL.

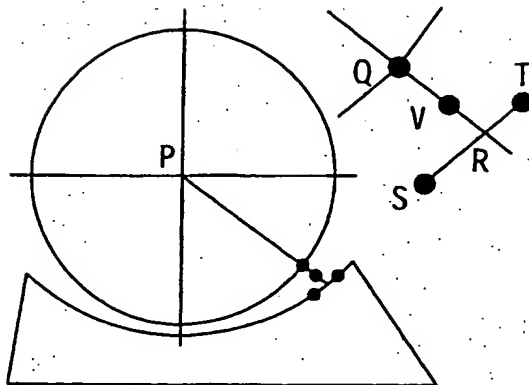
Fig.8

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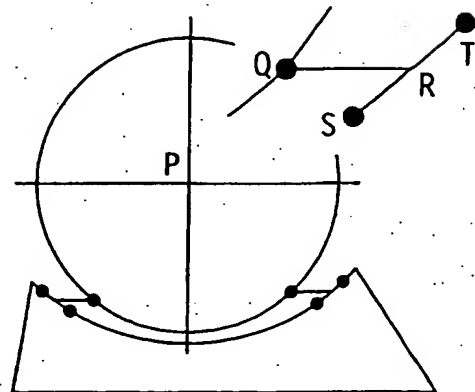
SYNTHESIS OF THE TIBIAL GUIDE SURFACE FROM THE ACCUMULATION OF POINTS OF THE FEMORAL GUIDE SURFACE AS THE FEMUR FLEXES FROM ZERO TO MAXIMUM.

Fig.9



MODIFICATION OF THE FEMORAL GUIDE SURFACE TO REDUCE LAXITY.

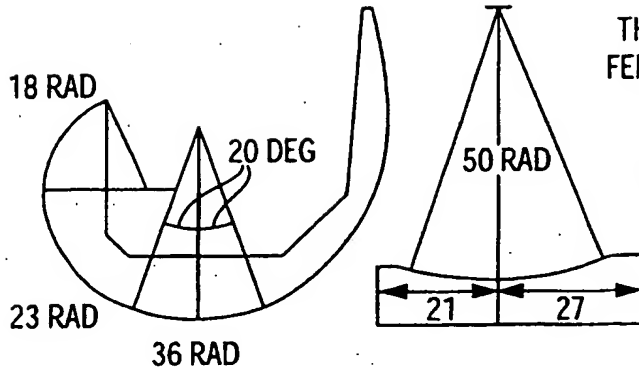
Fig.10



DETERMINATION OF THE LAXITIES IN THE ANTERIOR AND POSTERIOR DIRECTIONS.

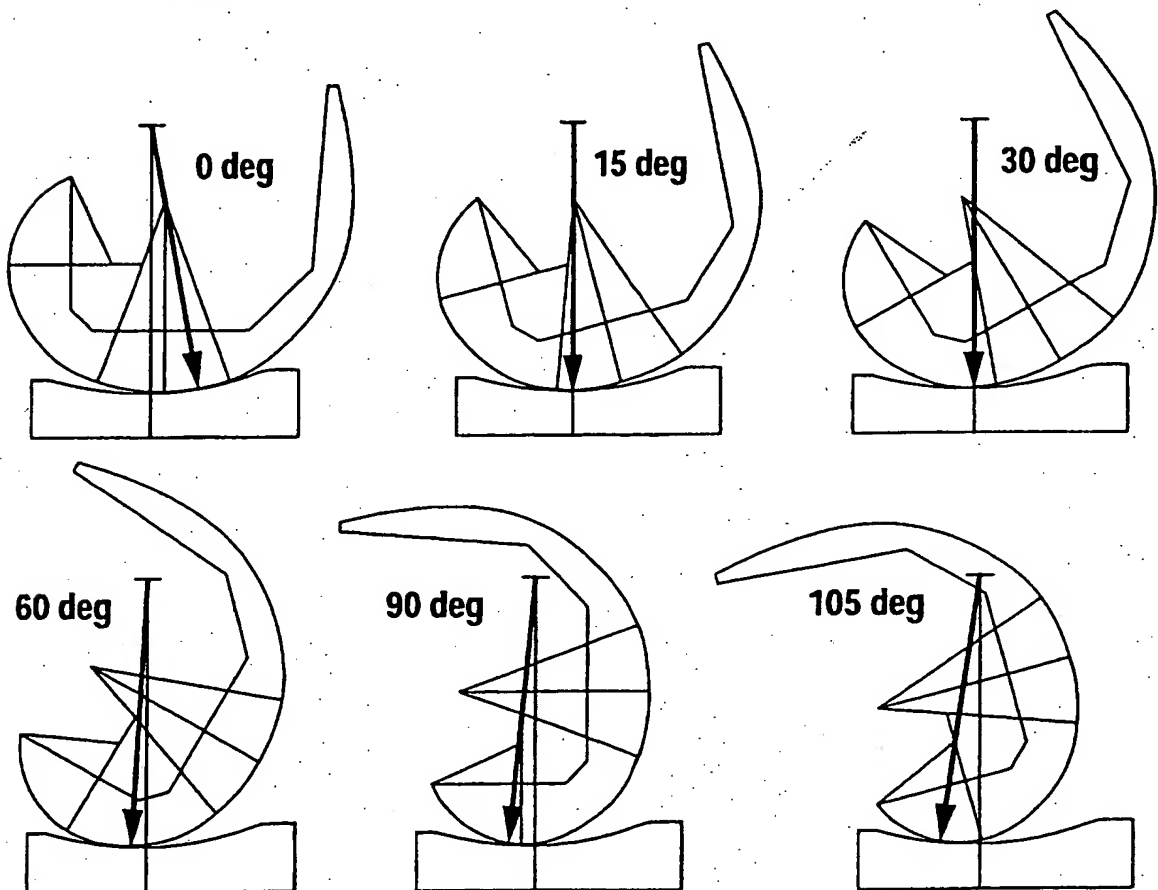
Fig.11

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THE SAGITTAL PLANE DIMENSIONS OF THE FEMORAL AND TIBIAL BEARING COMPONENT USED IN THE FOLLOWING FIGURES. THESE ARE TYPICAL DIMENSIONS ONLY, AND OTHER GENERALLY SIMILAR DIMENSIONS ARE APPLICABLE ALSO.

Fig. 12



THE GENERAL PATTERN OF THE LOCATIONS OF THE CONTACT POINTS (INDICATED BY ARROWS) DURING FLEXION FROM 0 DEG TO 120 DEG. IN EXTENSION THE CONTACT IS ANTERIOR OF THE BOTTOM OF THE TIBIAL DISH. AT 15 DEG AND 30 DEG THE CONTACT IS AT THE BOTTOM OF THE DISH. FROM 60 DEG TO 120 DEG THERE IS A POSTERIOR DISPLACEMENT, MORE RAPIDLY AS FLEXION PROCEEDS.

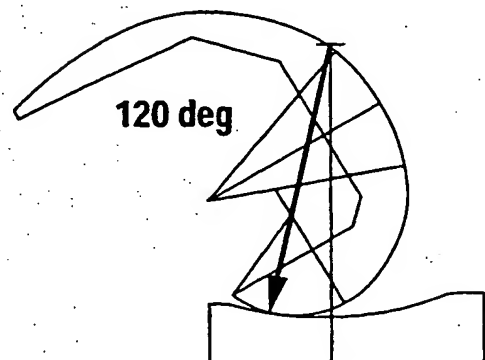
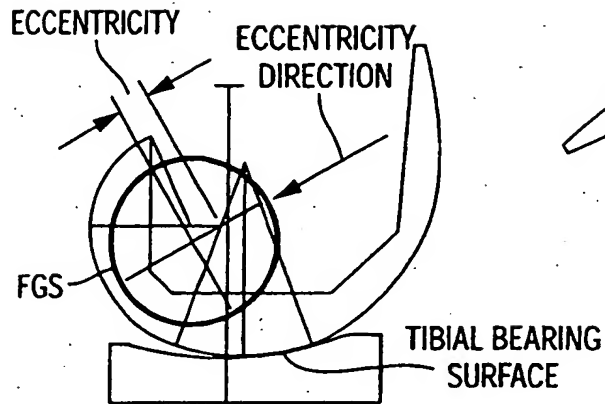
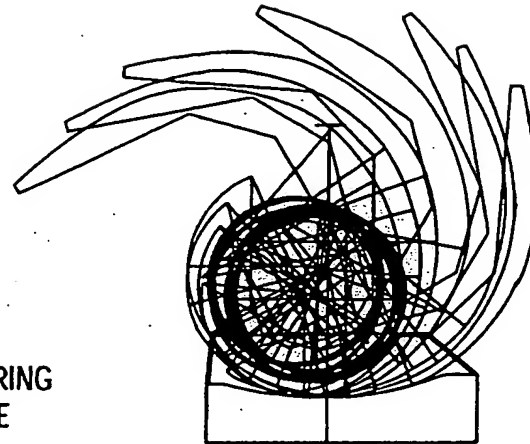


Fig. 13

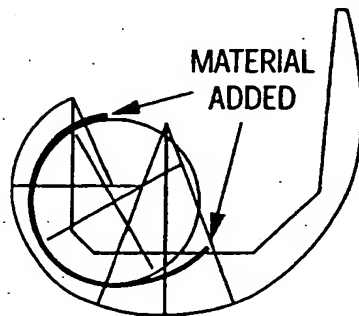
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THE INITIAL FGS IS DEFINED AS A CIRCLE WITH ECCENTRICITY ANGLE 30 DEG AND ECCENTRICITY 5 MM



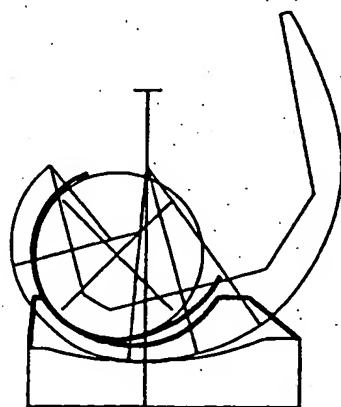
THE FEMORAL COMPONENT WITH ITS FGS IS PLACED INTO THE REQUIRED SUCCESSIVE POSITIONS ON THE TIBIAL BEARING SURFACE



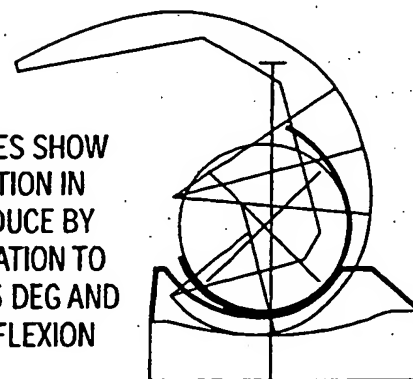
THE FGS IS THEN MODIFIED BY ADDING MATERIAL ANTERIORLY AND POSTERIORLY



THE OUTER LOCUS OF THE FGS DEFINES THE TGS, WITH THE ANTERIOR AND POSTERIOR HEIGHTS SPECIFIED



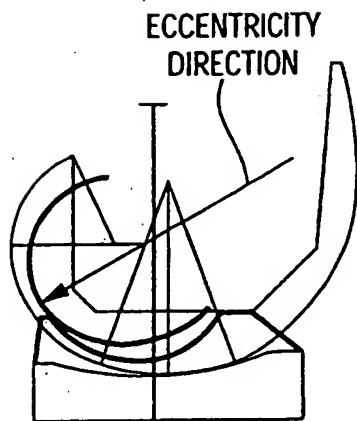
THESE FIGURES SHOW THE REDUCTION IN LAXITY PRODUCE BY THE MODIFICATION TO THE FGS, AT 15 DEG AND AT 115 DEG FLEXION



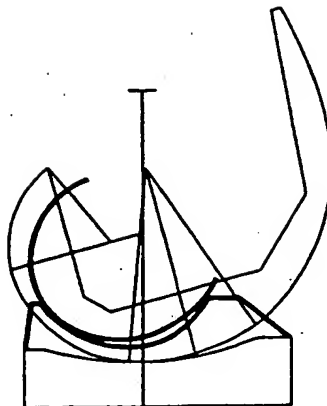
THE METHOD FOR GENERATING THE TGS FROM AN INITIAL FGS, ILLUSTRATED GRAPHICALLY.

Fig. 14

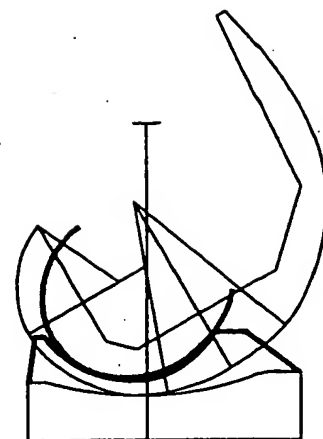
9/15



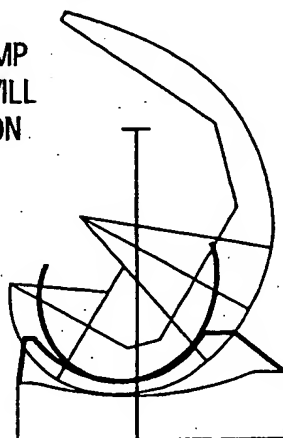
ABOVE THE FEMUR IS PREVENTED FROM DISPLACING POSTERIORLY BUT CAN DISPLACE ANTERIORLY. HOWEVER THE ANTERIOR RAMP OF THE BEARING SURFACES WILL LIMIT ANTERIOR TRANSLATION.



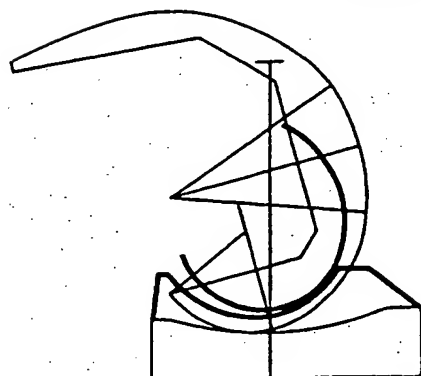
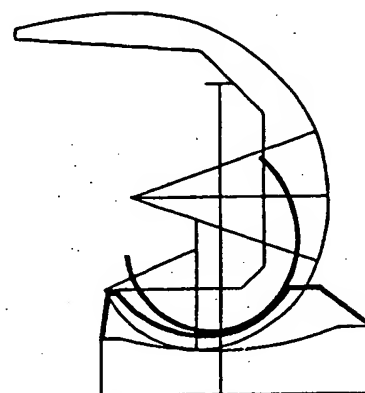
ANTERIOR TRANSLATION OF THE FEMUR IS PRODUCED FROM 15 TO 0 DEG FLEXION



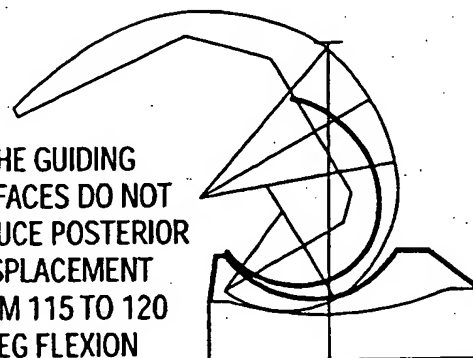
COMPLETE AP CONTROL



COMPLETE AP CONTROL



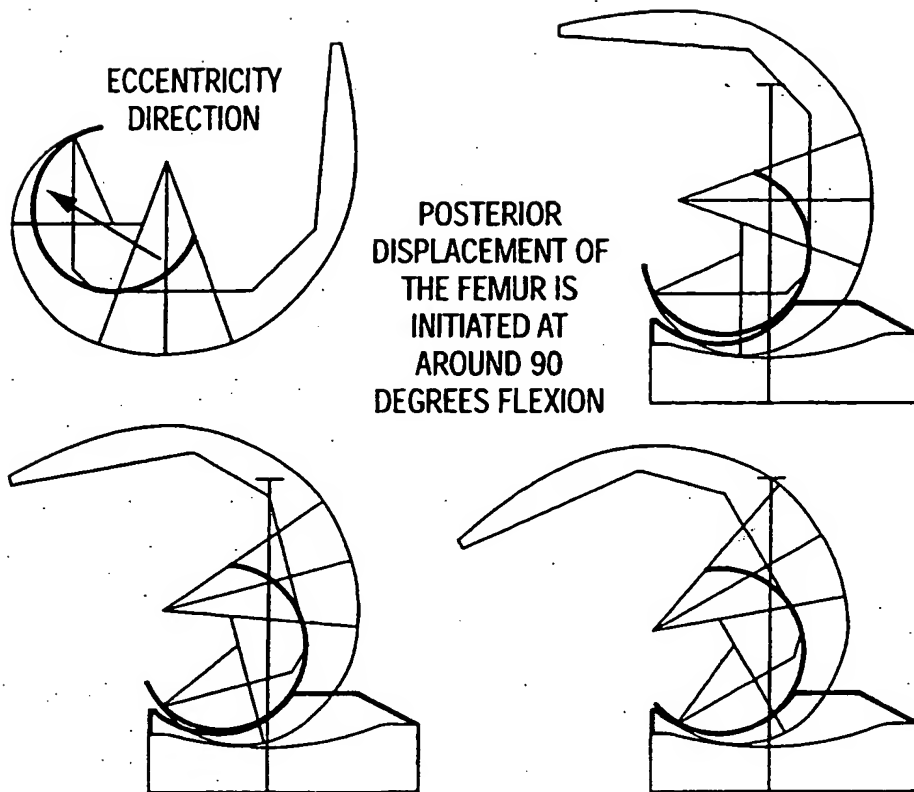
THE GUIDING SURFACES DO NOT PRODUCE POSTERIOR DISPLACEMENT FROM 115 TO 120 DEG FLEXION



GUIDING SURFACES GENERATED WITH THE ECCENTRICITY ANGLE AT 30 DEGREES BELOW THE HORIZONTAL AND AN ECCENTRICITY OF 5 MM. CORRECTIONS HAVE BEEN MADE AT EACH END OF THE FGS TO IMPROVE FIT WITH THE TGS.

Fig. 15

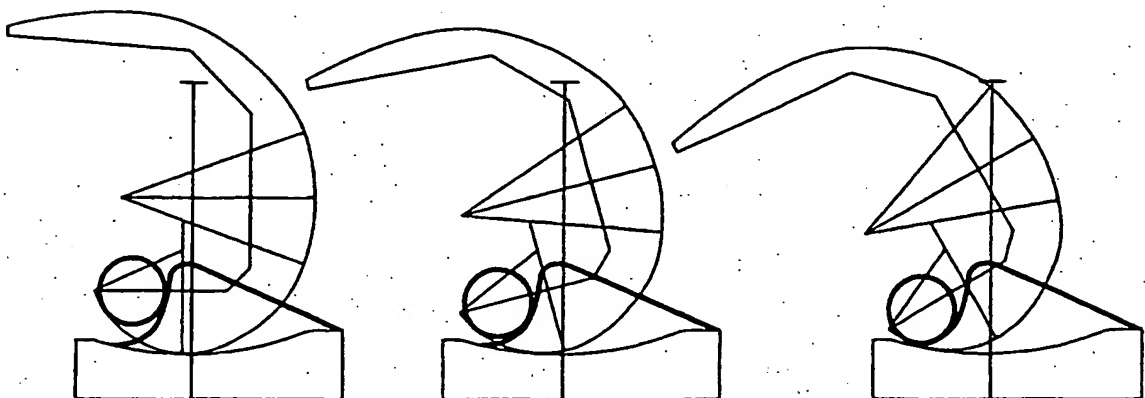
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POSTERIOR
DISPLACEMENT OF
THE FEMUR IS
INITIATED AT
AROUND 90
DEGREES FLEXION

WHEN THE ECCENTRICITY DIRECTION IS ABOVE THE HORIZONTAL (ARROW),
THE CONTACT POINTS ARE POSTERIORLY DISPLACED AFTER ABOUT 90 DEGREES FLEXION,
AND THERE IS CONTROL OF ANTERIOR-POSTERIOR DISPLACEMENT. AT FLEXION
ANGLES LESS THAN THIS, THERE IS NO CONTROL OF THE DISPLACEMENTS.

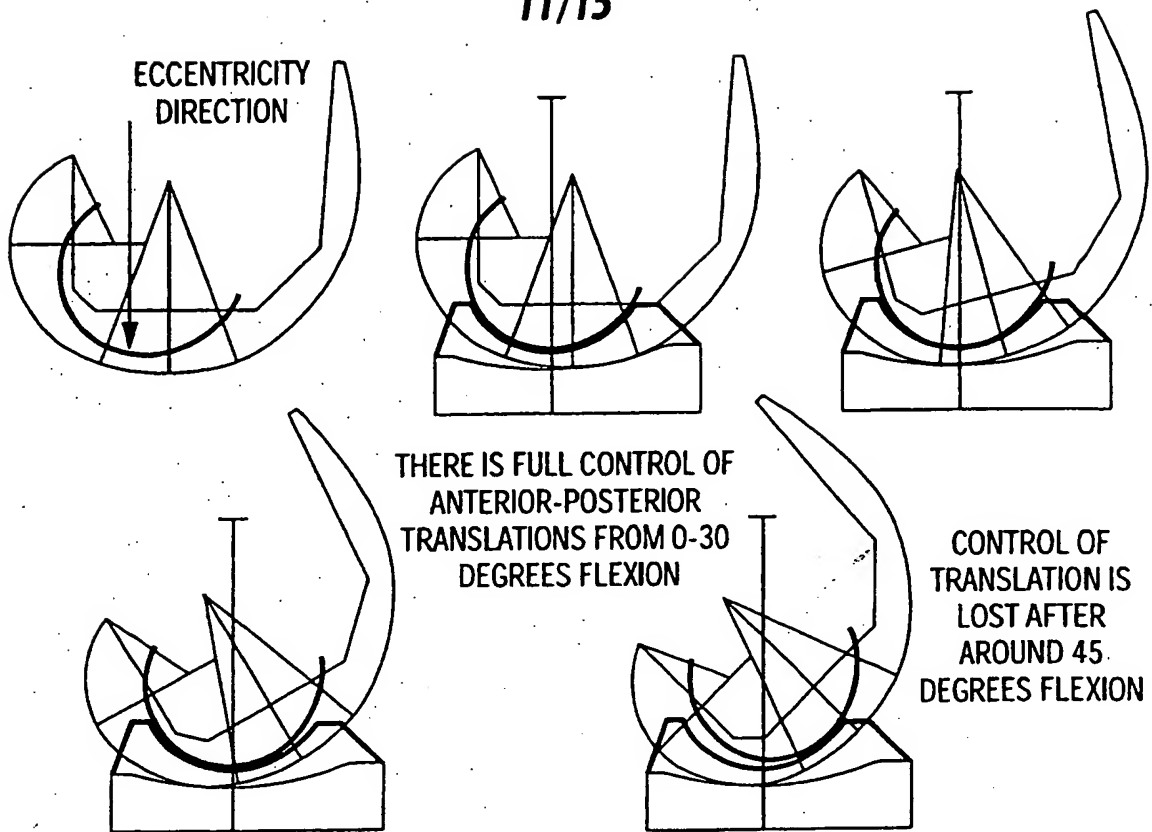
Fig. 16



WHEN THE RADIUS OF THE FGS IS REDUCED AND THE ECCENTRICITY INCREASED,
POSTERIOR DISPLACEMENT IS INDUCED AFTER AROUND 90 DEGREES FLEXION.
THIS IS THE PRINCIPLE OF THE POSTERIOR STABILISED TYPE OF DESIGN.

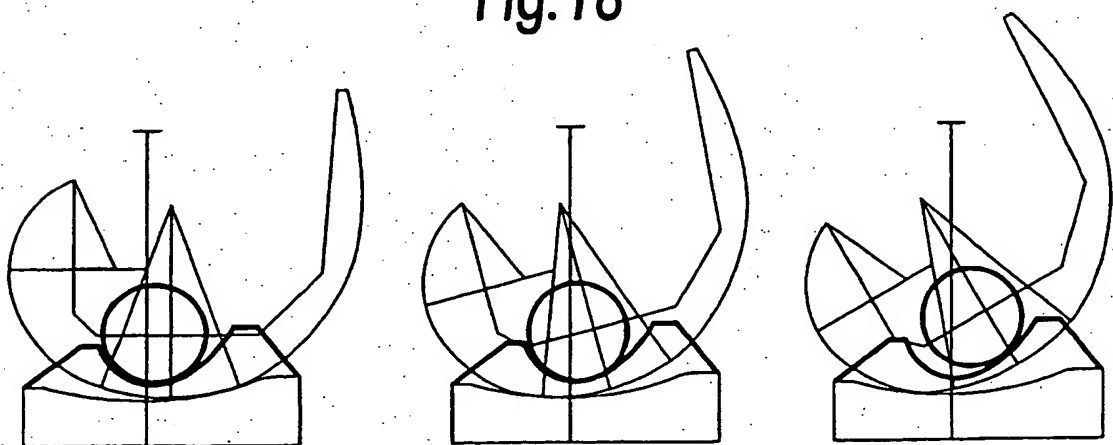
Fig. 17

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WHEN THE ECCENTRICITY ANGLE IS 90 DEGREES BELOW THE HORIZONTAL, THERE IS ANTERIOR TRANSLATION AS THE KNEE EXTENDS FROM 15 TO 0 DEGREES. THERE IS FULL CONTROL OF THE TRANSLATIONS UP TO AROUND 30 DEGREES FLEXION. AFTER AROUND 45 DEGREES THERE IS NO CONTROL OF THE TRANSLATIONS.

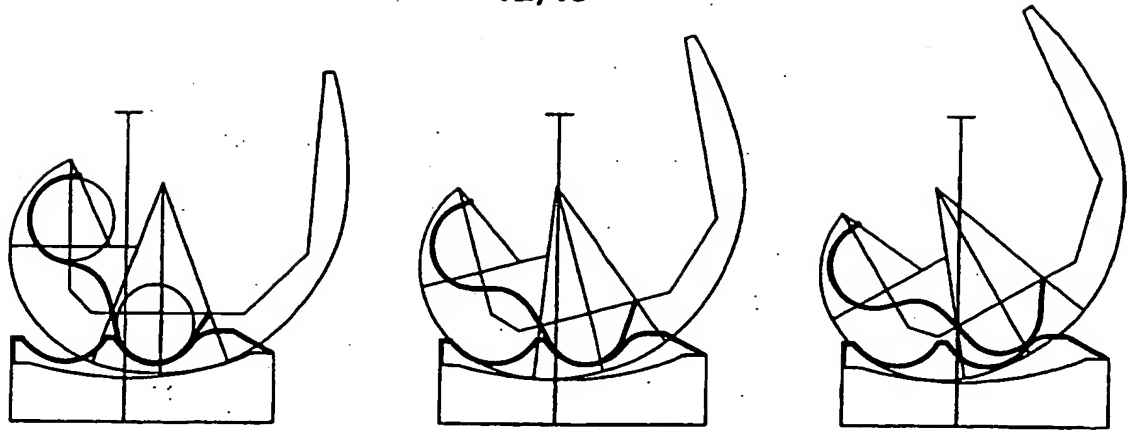
Fig. 18



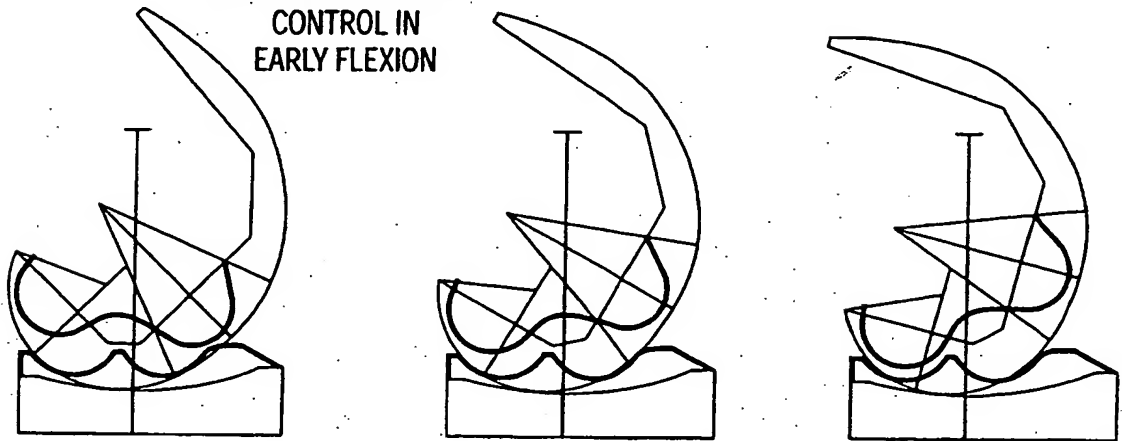
WHEN THE RADIUS OF THE FGS IS REDUCED AND THE ECCENTRICITY INCREASED, ANTERIOR-POSTERIOR TRANSLATION IS CONTROLLED IN THE FIRST 30 DEGREES OF FLEXION. ANTERIOR FEMORAL TRANSLATION IS CONTROLLED UP TO AROUND 45 DEGREES AFTER WHICH THERE IS NO CONTROL OF THE TRANSLATIONS.

Fig. 19

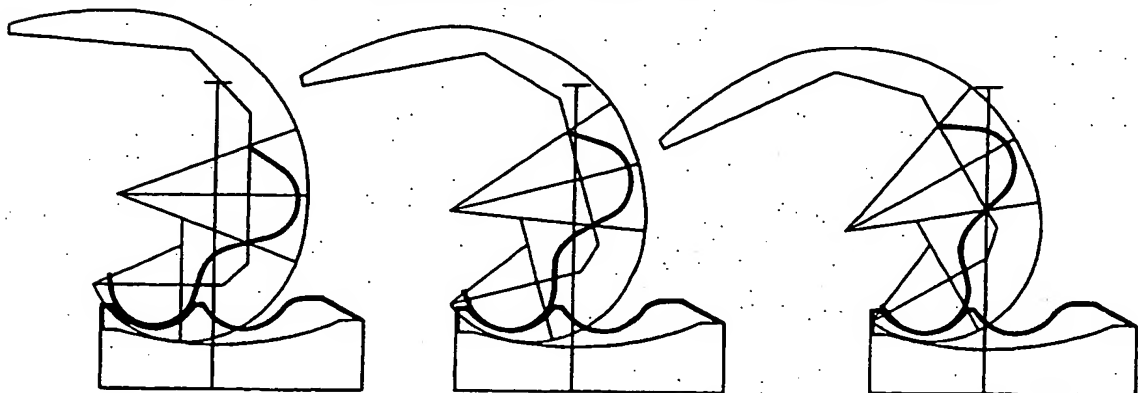
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ANTERIOR-POSTERIOR
CONTROL IN
EARLY FLEXION



NO ANTERIOR-POSTERIOR MOTION CONTROL IN THE MID RANGE FLEXION

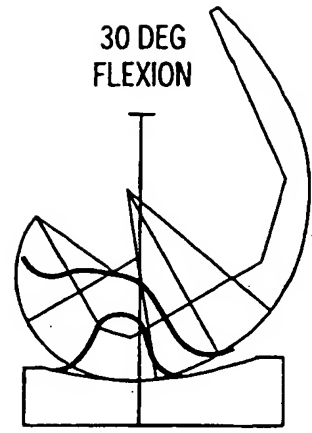
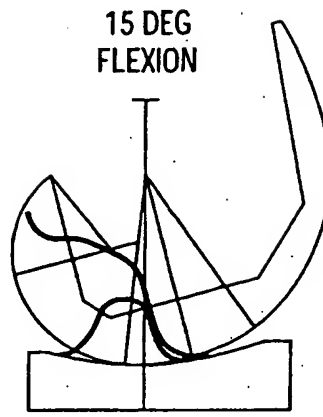
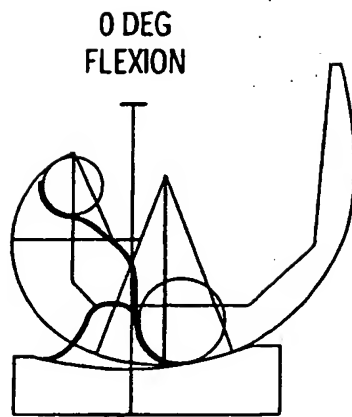


ANTERIOR-POSTERIOR CONTROL IN HIGH FLEXION

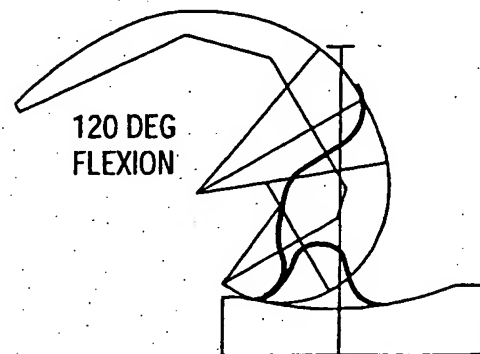
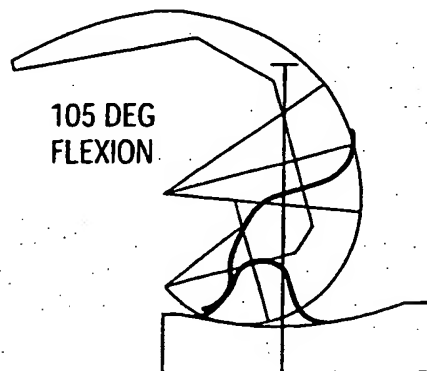
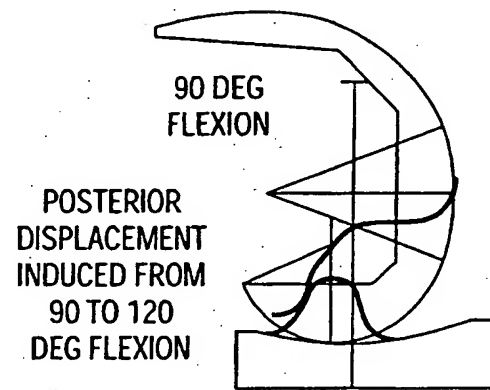
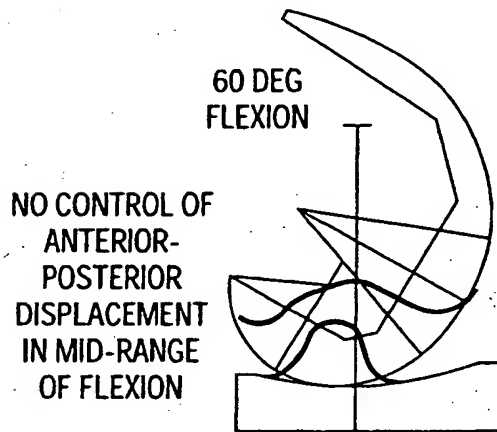
TWO SEPARATE PAIRS OF GUIDE SURFACES OF THE CONVEX FEMORAL / CONCAVE TIBIAL TYPE, ONE CONTROLLING ANTERIOR-POSTERIOR DISPLACEMENT TOWARDS EXTENSION, THE OTHER IN HIGH FLEXION. IN THE MID-RANGE, THE DISPLACEMENT IS CONTROLLED TO SOME EXTENT BY THE PARTIAL CONFORMITY OF THE FEMORAL-TIBIAL BEARING SURFACES.

Fig.20

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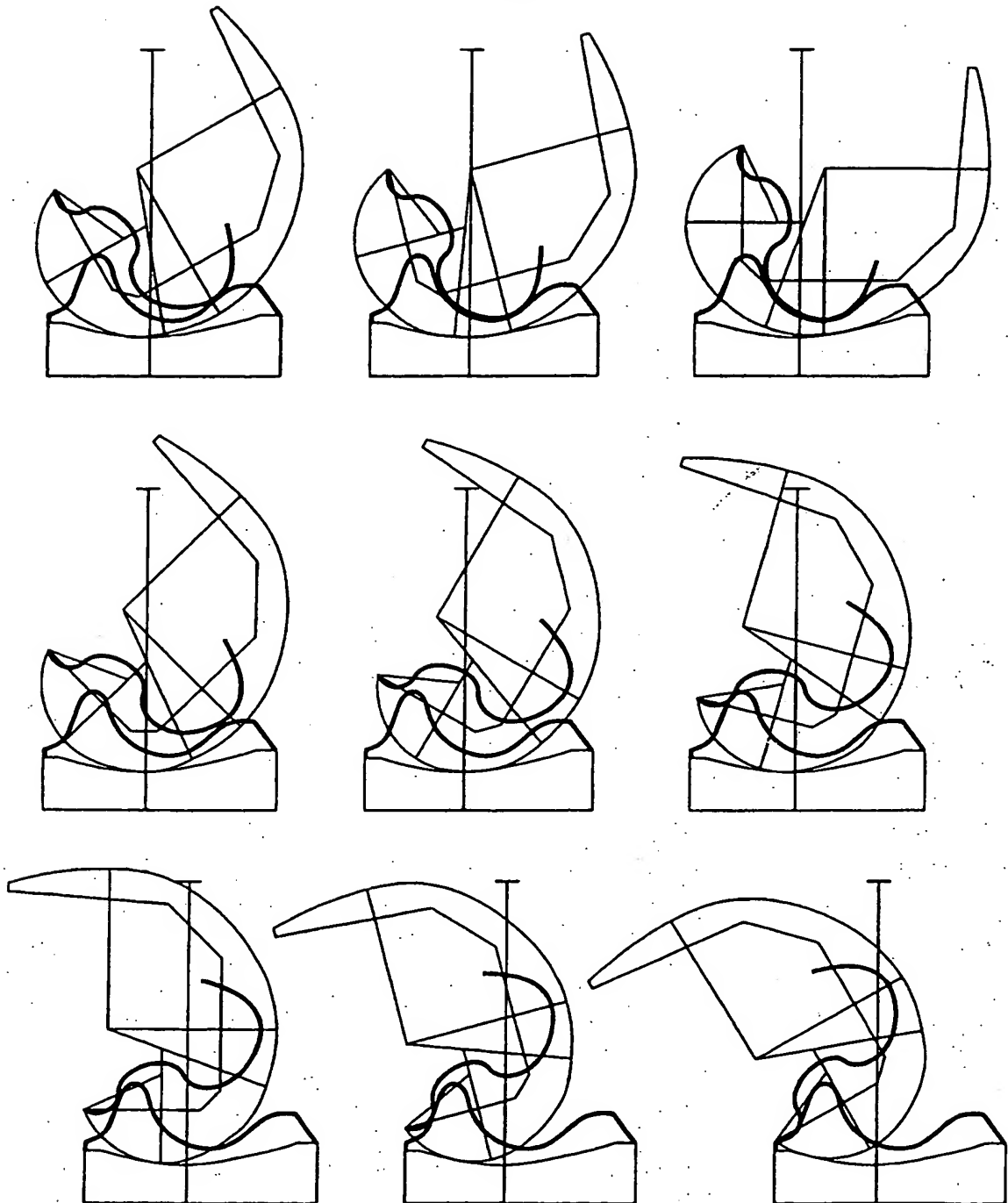
ANTERIOR DISPLACEMENT INDUCE
FROM 15 TO 0 DEG FLEXION



TWO SEPARATE PAIRS OF GUIDE SURFACES WITH MODIFIED RADII AND ECCENTRICITY, TO PRODUCE POSTERIOR DISPLACEMENT IN HIGH FLEXION AND ANTERIOR DISPLACEMENT TOWARDS EXTENSION. THE DISPLACEMENT IN THE MID-RANGE IS CONTROLLED TO SOME EXTENT BY THE PARTIAL CONFORMITY BETWEEN THE FEMORAL AND TIBIAL BEARING SURFACES.

Fig.21

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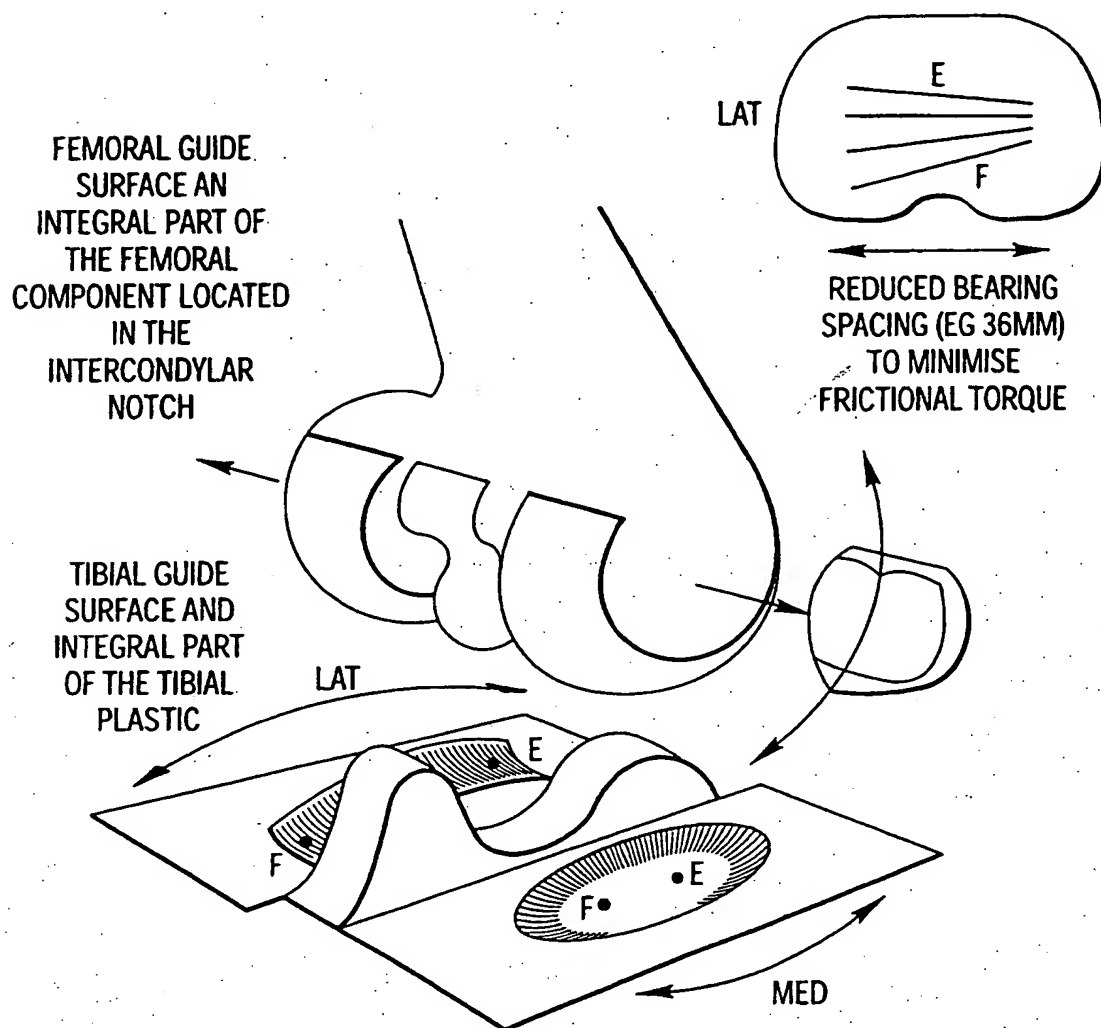


THIS SOLUTION USES TWO PAIRS OF GUIDE SURFACES. THE ANTERIOR SURFACES CONTROL ANTERIOR-POSTERIOR DISPLACEMENT UP TO 30 DEGREES FLEXION. THE POSTERIOR SURFACES INDUCE POSTERIOR FEMORAL DISPLACEMENT FROM 90 DEGREES FLEXION. THIS SOLUTION USES THE MOST ADVANTAGEOUS TYPE OF GUIDE SURFACES FOR THE REQUIRED BEHAVIOUR IN FLEXION AND EXTENSION.

Fig.22

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THE INCORPORATION OF DIFFERENT SHAPED LATERAL AND MEDIAL TIBIAL SURFACES TO ACHIEVE BOTH ROTATION AND TRANSLATION



THE CONDYLAR SURFACES ARE SUCH THAT THERE IS LIMITED AP DISPLACEMENT ON THE MEDIAL SIDE, AND 10-16 MM DISPLACEMENT ON THE LATERAL SIDE. THE GOAL IS TO BIAS THE MOTION SUCH THAT IN EXTENSION, THE CONTACT POINTS ARE CENTERED ON E, AND IN FLEXION, CENTERED ON F. THE INTERACTION OF THE GUIDE SURFACES PRODUCES ANTERIOR DISPLACEMENT IN EXTENSION, AND POSTERIOR DISPLACEMENT IN FLEXION. BECAUSE THE MEDIAL DISPLACEMENT IS LIMITED THERE IS ADDITIONAL DISPLACEMENT ON THE LATERAL SIDE. THIS ACTION WILL MIMIC THE ROTATIONAL AND DISPLACEMENT BEHAVIOUR OF THE NATURAL KNEE, AND WILL ASSIST IN PRODUCING A HIGHER RANGE OF FLEXION.

Fig.23

2335145

**KNEE PROSTHESIS HAVING GUIDE SURFACES
FOR CONTROL OF ANTERIOR-POSTERIOR TRANSLATION**

FIELD OF THE INVENTION

This invention relates to a total knee replacement prosthesis (TKR). Total knee replacement involves the surgical removal of the entire natural knee bearing surfaces and their replacement with artificial femoral and tibial components. Condylar TKRs usually comprise (a) a femoral component having a pair of condylar surfaces, generally resembling the natural joint surfaces, (b) a tibial component having a tibial platform fixed to the resected upper tibia, and (c) a bearing component usually of low-friction plastic material interposed between the femoral condylar surfaces and the tibial platform. The bearing component generally has dished surfaces for receiving the condylar surfaces of the femoral component. In 'fixed bearing' TKR designs, the plastic bearing component is fixed to the tibial platform. In 'mobile bearing' designs, the bearing component is allowed to rotate and/or translate on a polished upper surface of the tibial platform.

In all these types of TKR, anterior-posterior stability is provided by partial conformity between the femoral and tibial bearing surfaces, and sometimes in addition by retention of the posterior cruciate ligament or even by retention of both the posterior and anterior cruciate ligaments (Fig. 1). In some designs, called stabilisers, posterior stabilised, or posterior cruciate-substituting, some of the anterior-posterior stability is provided by an intercondylar cam. More particularly, these designs prevent forward subluxation of the femur on the tibia and also provide forced femoral rollback at high flexion (Fig. 2). The invention is concerned with a type of TKR where the anterior-posterior translation of the femoral component relative to the tibial platform during flexion-extension is controlled by intercondylar 'guide surfaces'. The invention can be applied to fixed bearing or mobile bearing designs.

In order to synthesise intercondylar guide surfaces, it is necessary to define first of all what is the desirable relative motion between the femoral component and the tibial platform. It is necessary to distinguish between rigid body motion, which

would be defined by the relative motion between a femoral origin and a tibial origin, and movement of the femoral-tibial contact points, which are independent of the femoral and tibial axis systems. We will focus on contact points. If there is rotation of the femur about the long axis of the tibia, the contact points will be in different anterior positions. In this case the average position of the contact point viewed in the sagittal plane of the tibia will thus be considered as the 'contact point'.

During passive flexion of the natural knee, the contact point moves from anterior to posterior, as represented by AP in Figure 3. This motion is determined by the shape of the condylar surfaces and by the cruciate ligaments. During different functions, the motions of the contact points will not necessarily correspond with the simple passive motion case described above, due to the anterior-posterior shear introduced by external forces and muscle forces. Nonetheless the simple case can usefully be used as a reference. The total posterior displacement of the contact point as the knee flexed from 0 -120° can be in the range 10-16 mm. Certain advantages of contact point location can be stated. At heel-strike in walking, there is an extending moment on the knee, equilibrated by the hamstrings. An anterior contact point is an advantage to provide a large lever arm for the hamstrings. In mid-stance, there is a flexing moment on the knee, equilibrated by the quadriceps, for which a central-posterior contact point provides an increased lever arm. The higher the angle of flexion and the flexion moment, as in stair climbing, the more posterior the contact point is an advantage. Finally, in order to maximise the range of flexion of the knee, a very posterior contact point is an advantage to avoid blockage of motion by the posterior soft tissues.

Ideally, a TKR should produce the motion described above, although a small amount of anterior-posterior laxity, such as 2-3 mm, might be permitted or even desirable in order to avoid a rigid control of motion which could cause loosening. On the other hand, excessive laxity is undesirable as it would increase wear.

Contemporary TKR's do not necessarily achieve the ideal motion proposed. For example, the motion of the contact points of relatively low conformity designs

depends upon the surgical technique in regard to component placement and ligament tensions. In more conforming designs, there is not always a mechanism for achieving posterior contact points in high. Even in the posterior stabilised designs, there is no mechanism for moving of the contact points - as the knee is extended. Furthermore, there can be high unwanted anterior-posterior shifts in contact points in highly conforming designs (Fig. 4).

THE INVENTION

It is, therefore, an object of the present invention to provide a TKR in which the femoral component provides for posterior displacement of the contact point with flexion and for a corresponding anterior displacement with extension, while maintaining adequate stability of the joint during such movements.

According to the present invention, there is provided a total knee replacement prosthesis which comprises:-

- a) a femoral component having a pair of condylar surfaces with a guide surface in between the lateral and medial bearing surfaces, which interacts with a guide surface on the bearing component noted below.
- b) a tibial plate fixed to the resected upper tibia, the upper surface adapted to receive the bearing component noted below.
- c) a bearing component interposed between the condylar surfaces and the tibial platform; and having dishd bearing surfaces adapted to support the femoral condylar surfaces and a guide surface projecting from the centre which interacts with the above-mentioned guide surface of the femoral component.

The intercondylar guide surfaces are shaped so that they control the anterior-posterior position of the femoral-tibial contact points during flexion-extension (Fig. 5). With the knee at zero flexion, the contact point is near to or anterior to the centre of the tibial bearing surface viewed in the sagittal plane. As flexion proceeds, the contact point moves posteriorly so that in full flexion, say 120°, the contact point is posterior to the centre of the tibial bearing surface. The total excursion of the contact point from 0-120° flexion is in the range 10-16 mm. At each flexion position, there

is allowed a certain anterior-posterior laxity, which can be up to 3 mm, to avoid rigid control of the motion, but it is part of the design concept that, in some design configurations, at some ranges of flexion angle, the condylar bearing surfaces themselves may combine with the guide surfaces in controlling the contact point location.

For illustration purposes, the tibial guide surface is shown as concave, having an anterior and posterior upward sweep, which engages in a convex guide surface in the femoral component to control the contact point location throughout the flexion range. The tibial guide surface may also include lateral and medial surfaces which engage with corresponding surfaces adjacent to the condylar surfaces of the femoral component.

In one embodiment of the invention, the tibial guide surface is an integral part of the bearing component (Fig. 6). If the bearing component is fixed to the tibial platform, sufficient lack of conformity in the sagittal plane is then required between the femoral and tibial bearing surfaces to allow the anterior-posterior translation of the contact points. It is also evident that to accommodate relative internal-external rotation occurring, further lack of conformity will be required. However, this rotation can be accommodated by pivoting the bearing component on the tibial plate, the so-called rotating platform configuration.

In another embodiment, the tibial guide surface may be an integral part of the tibial plate, or alternatively is a plastic component fixed relatively to the anterior-posterior direction on the tibial plate (Fig. 7). The bearing component may then take the form of two plastic bearing components each moveable on the tibial plate. The anterior-posterior movements of the bearing components are controlled by the intercondylar guide surfaces. If the tibial guide surface is narrower in the anterior-posterior direction, a single bearing component can be used with an elongated slot on the centre. In all these cases, the bearing components may be guided on the tibial plate in such a way as to leave clearance between the sides of the tibial guide surface and the bearing components, to permit combinations of rotational and anterior-

posterior movements. The guide surface may also be rotatably mounted on the tibial platform in order to provide internal-external rotation of the knee joint to a desirable degree. It can be seen in these embodiments, represented in Figure 7, that there can be close conformity between the femoral and tibial bearing surfaces, which will reduce the stresses and possibly the long-term wear.

SYNTHESIS OF GUIDE SURFACES

The aim is to achieve guide surfaces which allow only a small amount of anterior-posterior laxity, so as to control the position throughout the entire range of flexion. The method of designing the guide surfaces is by a series of incremental angular movements of the femoral component as described below with regard to Figures 8-11.

The geometry at zero flexion is shown in Figure 8. The sagittal outline of the bearing surface of the femoral component includes a posterior radius RF with centre O. This radius continues to around the distal point A, and the radius then increases to anterior point B. The tibial bearing surface is depicted with a larger radius, to enable movement of the femoral component to occur in an anterior-posterior direction. The bearing component is shown with minimum thickness MT and is assumed to be fixed to the tibial plate of length TL. At zero flexion, the femoral-tibial contact point is located a distance AL from the front of the plate. The posterior displacement of the femoral component up to maximum flexion is PT. This is rigid body motion of the femur. As noted previously, for partially conforming femoral-tibial surfaces, the displacement of the contact points will be greater than PT.

In this example, the guide surfaces in the intercondylar notch are defined such that the Femoral Guide Surface (FGS) is convex, and the Tibial Guide Surface (TGS) is concave. The latter is fixed in an anterior-posterior direction with respect to the bearing component and the tibial plate, such that by its interaction with the Femoral Guide Surface, the femoral component can be made to translate relative to the tibia. The starting point for the shape of the FGS is a circular arc of radius RG and centre P which is offset from O by a distance EC at an angle of TH from the horizontal. As the

femur flexes from zero to maximum, it is required that the centre of the femoral component 0 displaces posteriorly by PT, moving continuously with flexion. The movement can be linear or non-linear with flexion.

The problem is to synthesise the TGS, which is depicted in Figure 8 as a concave arc of as yet unspecified shape. The heights of the TGS at the anterior and posterior are defined by a stability requirement when the femoral component is subject to a shear force, such that the FGS is pressing against the TGS at points C or D. If V is the vertical force across the knee and H is the shear force, stability is just achieved when angles AD and AC are given by:

$$\tan (AC) = V/H, \tan AD = V/H$$

For normal knee forces, the angles will be 200 or more. The angles AC and AD do not need to be the same. The height of points C and D about the initial contact A is then calculated, HT. It is required that posterior displacement be positive for all angular increments, which, by inspection, requires that the line OP lie in the third quadrant.

The following is referred to the XY axis system with origin A. Discrete points are calculated around the FGS at small angular increments, so as to closely represent the circular arc.

Points at zero flexion are stored with a Y value below HT, the maximum height of the TGS. The femur is then flexed through an angle DF, and displaced a small distance posteriorly according to the chosen relation between displacement and flexion angle.

The co-ordinates of all of the points on the FGS are then transformed according to a mathematical transformation matrix.

Again, points are stored with a Y value less than HT. The femur is then flexed and displaced through a further increment; the points on the FGS are again transformed, and those with a Y value less than HT are stored. This process is repeated until the maximum flexion angle FM. Typical increments are 50 up to a maximum flexion of 1200.

At this stage a cluster of stored points is obtained (Fig. 9). The initial tibial guide surface TGS is given by the exterior locus of the points. To determine the points on this locus, the following algorithm is used. The point with the minimum Y value is determined, L (XL, YL). The next point in a positive X direction M (XM, YM) is found by a searching routine such that the slope of LM is a minimum.

This process is continued along the positive X direction until no further points can be found. The same process is used to determine the points at $X < XL$. The points can then be connected with splines to form a smooth curve for the TGS, but for this analysis an approximation is made with short line segments joining successive points, with minimal error.

It is found that at any general flexion angle, when the FGS is superimposed on the TGS, there is an anterior and posterior space such that displacements could occur and there would not be a unique position of the femur on the tibia. This 'laxity' can be reduced as follows. Conceptually it can be visualised that the anterior region of the TGS could be formed as the posterior part of the FGS sweeps over at high flexion angles. It is possible therefore that this anterior region could be filled by an expanded anterior part of the FGS, which would not interfere because it would move out of the TGS in early flexion. To examine this possibility, the femur is flexed from zero to FM in the same angular increments as before, and at each angle, each point Q on the FGS for $YQ < HT$ is identified (Fig. 10).

The intersection of PQ with a line segment ST on the TGS is calculated, point R. However, there may be an upper limit RMAX for the radius of the FGS based, for example, on the required dimensions for the patellar groove. Point V is such that $PV = RMAX$. The co-ordinates of Q are changed according to:

If $PR < RMAX$, then $XQ = XR$, $YQ = YR$

If $PR > RMAX$, then $XQ = XV$, $YQ = YV$

By carrying out this procedure it is found that the FGS is expanded in both the leading and trailing regions. The algorithm assures that expansion of the trailing region of the FGS in early flexion is subsequently reduced in late flexion if there is interference with the anterior TGS. It is evident that further iterations for either the FGS or TGS do not result in any further changes. Even after this procedure, in general, at all angles of flexion, there is still some anterior or posterior laxity possible between the FGS and the TGS.

This laxity is calculated at each of the angular increments (Fig. 11). Again, each point on the FGS was examined for which $YQ < HT$. The intersection of a horizontal line through a line segment on the TGS is calculated, and the length QR calculated. QR would be the anterior laxity of the femur if point Q was the first point to contact the TGS. The values of QR for all points on the FGS to the right of L are calculated. The minimum value is the relevant value of the anterior laxity.

The values of anterior and posterior laxity at a succession of angular increments from zero to maximum flexion are then used to formulate criteria for determining the best design of the FGS and TGS. The variables were the radius of the femoral guide surface RG and the eccentricity angle TH. The first criterion was to minimise the arithmetic sum of the laxities. This minimises the overall AP laxity throughout motion, but gives equal weight to a small number of large displacements or a large number of small displacements. The second criterion was to minimise the sum of the laxities squared. This is similar to the first criterion but is biased against large laxities. The third criterion was to minimise the maximum laxity value. The design problem is then stated as:

Determine the optimum design of the FGS and TGS, according to the three criteria, in the ranges of TH between 0 and 60° , and of RG between 10 and 18 mm based on geometrical considerations.

It is noted that the eccentricity EC is not treated as a variable, as it is determined by the choice of the posterior displacement PT and the starting angle of the FGS, TH. It was found that for all criteria, an eccentricity angle of 30° gave the least

laxity. The radius of the FGS made little difference. The highest laxities occurred at the extremes of motion and the least laxities at mid-range. For eccentricity less than 30° , the laxity increased at zero flexion and reduced at full flexion. For eccentricity greater than 30° , the opposite was the case.

The sagittal geometry of the femoral and tibial bearing surfaces can be specified in numerous ways. Certain geometries will be more suited to mobile bearing configurations, notably those with high femoral-tibial conformity, while reduced conformity is more suitable for fixed bearing or rotating platforms where anterior-posterior translation of the femur on the tibia is required. For the purposes of this analysis, the latter are specified (Fig. 12). The distal radius is continued posteriorly by 20° so that the same femoral-tibial conformity can be maintained during a walking cycle. In the mid-range of flexion the smaller radius contacts, while in high flexion, an even smaller radius comes into play in an effort to maximise the flexion angle of the knee.

A typical required sequence of femoral-tibial contact points as the knee flexes from 0 to 120 degrees is shown in Fig. 13. As the knee moves into extension from 15 degrees, in many common activities there is a requirement to prevent further extension, which is provided by action of the hamstrings or gastrocnemius. To obtain efficiency of this action, an anterior contact point is required at 0 degree flexion. As the knee flexes, a contact point just posterior of the centre of the tibial bearing surface provides adequate lever arm for the quadriceps. Beyond 60 degrees, an increasingly posterior contact point further increases the quadriceps lever arm. Finally, beyond 105 degrees, a more rapid posterior translation of the contact point is an advantage for maximising the range of flexion. The sequence of contact points is represented generally, and the precise locations can vary by say 2-3 millimetres from those shown.

Given a typical sagittal geometry for the femoral and tibial bearing surfaces, and the sequence of contact points, the rigid body motion of the femur can be determined geometrically. The method for synthesising the TGS for a given FGS has been described above. The method can be illustrated graphically (Fig. 14). The

femur is positioned on the tibial bearing surface in the sequence of positions shown in Figure 13. The TGS needs to accommodate the multiple positions of the FGS. The TGS is then defined by the locus of the convex side of the multiple FGS positions. The anterior and posterior heights of the TGS are defined based on the required stability, or subluxation height. As described previously, the FGS can be subsequently modified by adding material at the anterior and posterior, which reduces the laxity at the extremes of motion. The resulting FGS and TGS still allow some laxity at the extremes, but overall, there is limitation of both anterior and posterior displacements, more especially in the mid-range of flexion.

Using the method for generating the femoral and tibial guide surfaces described above, the configuration is shown which produces the least overall laxity, regardless of which criterion is used (Fig. 15). The FGS is convex and the TGS concave. With the knee in extension, there is a small gap allowing the contact point to slide anteriorly. In the mid-range of flexion there is complete control of anterior-posterior displacement up to 105 degrees. With this basic configuration of the FGS and TGS, a useful posterior translation of the contact points occur with flexion. However, at 120 degrees flexion, the Guide Surfaces do not produce the required posterior translations. This example illustrates the problem of obtaining guided motion throughout the entire flexion range.

To obtain more positive control in higher flexion, the eccentricity angle of the FGS can be set at 0 degree i.e. directed posteriorly, or even at 30 degrees above the horizontal (Fig. 16). A suitably large posterior displacement of the contact point can be achieved, while there is control in both the anterior and posterior directions. The posterior ramp of the TGS is shallower than ideal, but control of posterior displacement is not regarded as being quite so important because the contact is likely to roll and slide down the slopes of the TGS and the posterior tibial bearing surface as the knee starts to extend from the fully flexed position. The combination of FGS and TGS shown in Figure 16 is effective only after about 7500 flexion. At lower flexion angles, anterior-posterior control is lost.

A variation of the above is achieved by reducing the radius and increasing the eccentricity of the FGS (Fig. 17). Here, after around 90° flexion, a high posterior displacement can be achieved. The shapes resemble some posterior stabilised designs. With an even smaller radius, the FGS and the TGS resemble yet other posterior stabilised designs.

At the opposite end of the flexion range, FGS and TGS surfaces can be produced which control the motion in early flexion, but not in late flexion (Fig. 18). This is achieved when the eccentricity angle is 90° below the horizontal. Anterior-posterior control is lost after around 45° of flexion. When the radius of the FGS is reduced and the eccentricity increased, anterior-posterior control can be achieved at low flexion (Fig. 19). The anterior displacement is higher, but control is lost at a lower flexion angle than the configuration of Figure 18.

Regarding utility of the configurations of Figures 14-17, those of Figures 14 and 15 are preferred if a high flexion angle is regarded as most important, while those of Figures 16 and 17 are preferred if the muscle lever arms in activities with small flexion angles, such as level walking, are regarded as most important. However, none of these configurations satisfies the ideal requirements throughout the full range of flexion. Two separate pairs of FGS and TGS surfaces, however, might achieve control at both low and high flexions. For example, if the FGS and TGS of Figure 17 was combined with the FGS and TGS of Figure 19, a bi-lobed convex FGS is produced, which generates a bi-convex TGS (Fig. 20). The interaction of the combined FGS with the TGS resembles the action of spur gears. The anterior pair controls the anterior-posterior displacement from around 0-30 degrees flexion, while the posterior pair provides control after about 90° flexion. It is not possible to achieve control in the midrange of flexion. A disadvantage of the configuration is the shallow concavities of the TGS, which could allow subluxation. This would be particularly problematic in high flexion, which is known for the tendency of the femur to sublux anteriorly when the hamstrings are active. This problem can be addressed

to some extent by reducing the radius of the posterior FGS, which generates a higher protuberance in the centre of the tibia.

If the radii of the anterior and posterior FGS's are reduced, the configuration shown in Figure 21 is produced. The anterior and posterior concavities of the two TGS's disappear, to be replaced by a large central protuberance. As the knee reaches high flexion, the contact points displace posteriorly at a high rate with flexion angle. Like the action of a posterior stabilised knee, this can be proposed as an advantage. As the knee is brought into full extension, the femoral-tibial contact point moves anteriorly at a high linear rate with extension, a similar action to that at high flexion. The advantage of the configuration is that there is a very stable FGS-TGS interaction with little risk of subluxation or lack of proper engagement, throughout the entire flexion range. The disadvantage is that achieving the required contact points towards extension will require accurate positioning of both the femoral and tibial components. In addition, there is no positive mechanism causing posterior translation of the contact points in early flexion, except that due to rolling and sliding down the anterior slope of the tibial bearing surface.

A satisfactory solution can be reached by again using a double pair of FGS-TGS surfaces (Fig. 22). The posterior FGS is of small radius and high eccentricity to achieve a high rate of posterior displacement in high flexion. The anterior FGS is of medium radius and eccentricity to provide complete anterior-posterior control in early flexion. There is an acceptably low rate of anterior displacement with angle so that high accuracy of placement of the femoral and tibial components is not required. Of all the configurations shown hitherto, this is proposed as being the most favourable for achieving the overall objectives of Guiding Surfaces.

Figure 23 illustrates one way in which the lateral and medial tibial surfaces can be shaped in order to permit translation of the femoral component and at the same time to induce rotation in a way which minimises movement of the natural knee. The intercondylar femoral guide surface is shaped to interact with the tibial guide surface

centrally located between the condylar bearing surfaces on the tibial bearing component. The interaction is such that in extrusion the contact points are centered on point E in extension and on point F in flexion. Because there is a greater degree of translation on the lateral side than on the medial side, rotation of the femoral component on the tibia component will be biased about an axis displaced towards the medial side.

CLAIMS

1. A condylar total knee replacement prosthesis which comprises:
 - (a) a femoral component having a pair of condylar surfaces;
 - (b) a tibial component having a tibial platform;
 - (c) bearing components interposed between the condylar surfaces and the tibial platform and having dished bearing surfaces adapted to support the femoral condylar surfaces, said femoral component having an intercondylar femoral guide surface adapted to engage the corresponding tibial guide surface, said tibial guide surface and said femoral guide surface being shaped so as to cause the femoral component to be displaced posteriorly during flexion, and displaced anteriorly during extension, and said tibial guide surface being fixed with respect to the tibial platform in an anterior-posterior (A-P) direction.
2. A prosthesis as claimed in Claim 1 where the femoral guide surface is convex and the tibial guide surface is concave.
3. A prosthesis as claimed in Claim 1 where there are two pairs of femoral and tibial guide surfaces, both the anterior and posterior pairs consisting of convex femoral guide surfaces and concave tibial guide surfaces.
4. A prosthesis as claimed in Claim 1 where there are two pairs of femoral and tibial guide surfaces, the anterior and posterior pairs consisting of convex femoral guide surfaces of small radius (less than 5 mm) and a tibial guide surface consisting of a central post with convex anterior and posterior surfaces.
5. A prosthesis as claimed in Claim 1 where there are two pairs of femoral and tibial guide surfaces, the anterior pair consisting of a convex femoral guide surface and a concave tibial guide surface, the posterior pair consisting of a convex femoral

guide surface of small radius (less than 5 mm) and a tibial guide surface consisting of the posterior surface of a post projecting from the tibial component.

6. A prosthesis as claimed in any one of the preceding claims in which the posterior displacement of the contact point during the full range of flexion is in the range of 6 to 16 mm.

7. A prosthesis as claimed in Claims 1 to 6 wherein the tibial guide surface is an integral part of the bearing component.

8. A prosthesis as claimed in Claims 1 to 6 wherein there is sufficient laxity between the femoral bearing surfaces and the bearing component to allow for about ± 12 degrees of internal/external rotation.

9. A prosthesis as claimed in Claims 1 to 6 wherein the bearing component is mounted on the tibial platform so as to allow internal-external rotation.

10. A prosthesis as claimed in Claims 1 to 6 where two separate lateral and medial bearing surfaces are free to slide in an A-P direction on the tibial plate.

11. A prosthesis as claimed in Claims 1 to 6, and Claim 10 where the femoral bearing surfaces are in substantial contact with the tibial bearing surfaces, due to anterior notching of the lateral and medial extremes of the femoral bearing surfaces.

12. A prosthesis claimed in Claims 1 to 6, and Claims 10 and 11 where the tibial guide surface is free to rotate on a vertical axis about the centre of the tibial plate.



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Application No: GB 9805226.9
Claims searched: 1-12

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Examiner: Craig R. Thomson
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Patents Act 1977 Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK CI (Ed.Q): A5R (RAK)

Int CI (Ed.6):

Other:

Documents considered to be relevant:

| Category | Identity of document and relevant passage | | Relevant to claims |
|----------|---|---|--------------------|
| E, X | GB 2324249 A | (WALKER) see especially p1, line 1- p2, line 18, claim 11 and figures 1A and 10 | 1, 2, 6 |
| X | GB 2301538 A | (CORIN MEDICAL) see especially claim 1, figure 4 and p6, line 5 - p7, line 6 | 1 |
| X | GB 2067412 A | (NY SOCIETY) see especially claim 1 and figure 7 | 1 |
| X | GB 1507309 | (WHITE) see especially figures 1-4 | 1 |
| X | US 4353136 | (POLYZOIDES et al.) See especially claim 1, column 3, lines 42-59 | 1 |
| X | US 4209861 | (WALKER et al.) See especially column 2, lines 5-30 and figure 10 | 1 |

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